

Remarks

Claims 10-23 are pending and stand rejected. Applicant has amended claims 12 and 13 and added new claims 24-26. No new matter is added by these amendments.

Claim Rejections – 35 U.S.C. §112

The Examiner has maintained the rejection of claim 12 and additionally rejected claim 13 under 35 U.S.C. §112, ¶1, for failing to comply with the enablement requirement. Applicant herein has amended claims 12 and 13 to remove the language of “preventing” to overcome this rejection.

Claim Rejections – 35 U.S.C. §103

The Examiner has maintained the rejection of claims 1-23 under 35 U.S.C. §103(a) as being unpatentable over the combined disclosures of Runge *et al.* and Woerwag *et al.*, repeating the rejection from the prior Office Action received in this Application.

The present invention is a treatment for the skin itself, addressing the breakdown of collagen and elasticity of the skin caused by the presence of glycated proteins in the skin (e.g. inflammation, wrinkles, brown spots or lipofuscin, and irritation, and erythema). See Application ¶ [0009]. Once these glycated proteins are reduced and/or their formation is prevented, damaging effects on the skin are removed such that elasticity and a supple feeling is returned to the skin, fine lines and wrinkles are lightened, and skin coloring evens out. *Id.* at ¶ [0010].

In contrast, Woerwag addresses a pharmaceutical composition containing benfotiamine taken up in and distributed throughout a carrier which is applied topically to the skin. See Woerwag Abstract. The pharmaceutical composition is used to treat rheumatic disorders, general joint and muscle pains, root irritant syndrome of the spinal

column, HWS-syndrome, shoulder-arm-syndrome, symptoms resulting from polyarthritis, tennis elbow, stiff neck, lumbago, sciatica, disc pain, arthroses, polyneuropathy, neuritis, migraines, neuralgia, shingles (a virus of the nerve cells), and facial paralysis. *Id.* (N.B. none of these are disorders of the organ of the skin) Woewarg merely discloses benfotiamine for its known properties as a lipid soluble analog of vitamin B1. Benfotiamine is known in the art as a treatment for such rheumatic disorders, and Woerwag merely presents a transdermal delivery means. *Id.* Per the disclosure in the Abstract in Woewag, by applying benfotiamine topically to the *body parts affected*, where it is then converted into thiamin or cocarboxylase, it is possible to achieve targeted local action on that *body part*. With such topical delivery, the transport route is shorter than that when applied in the form of an oral drug, less thiamine is produced before the benfotiamine reaches the affected part of the body and the cells to be treated, thus the action due to thiamine is maximized on the body part. *Id.*

Hence, Woerwag does not teach or suggest benfotiamine for action upon the skin, nevermind improvement of skin, wherein the composition reduces the quantity of glycated proteins (claims 10, 11, 13, 21, and 25) or reduces the formation of glycated proteins (claims 12, 22, 24, and 26) as is presently claimed. Rather, Woerwag merely discloses delivery through then skin (such that benfotiamine passes through the skin without acting upon it) to reach internal body parts for action thereupon, delivering well-known benfotiamine therapy internally, just in alternate delivery form to the known oral therapies.

Further, Runge fails to teach or suggest each and every element of the present claims. Runge merely includes a cursory disclosure of benfotiamine as one of several potential *adjunct* ingredients in carotenoid formulations for cosmetic preparations and supplements. See Runge col. 3, lines 3-4. In Runge *et al.*, there is no discussion of the properties or effects of benfotiamine alone or when incorporated with any of these other several listed potential adjunct ingredients. There is no disclosure of benfotiamine to be

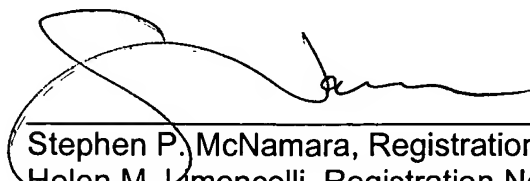
used as an active agent in a topical composition, nor for the specific purpose to act upon the skin, nor achieve beneficial effects by reducing glycated proteins in the skin.

There is no disclosure or suggestion in neither Woerwag or Runge of a method of use of an effective amount of benfotiamine in a topical composition to act upon the skin, wherein the composition reduces formation of glycated proteins in the skin as is claimed by Applicant. Hence, Woerwag and Runge, each alone and in combination, fail to disclose, teach or suggest the methods as claimed in the present invention.

There is nothing in the disclosure of Runge nor Woerwag that would lead one of skill in the art to use benfotiamine in a composition for beneficial treatment of the skin by reducing glycation, treating damage caused thereby, or treating aging caused thereby, by applying a composition comprising an effective amount of benfotiamine, wherein the composition reduces formation or the quantity of glycated proteins.

Applicant respectfully asserts that in light of the foregoing amendment and remarks, the Response renders all pending claims in condition for allowance, and early notice of such is requested.

Respectfully submitted,



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